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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,752	10/11/2005	Harald Kretschmann	F-8812	2610
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JORDAN AND HAMBURG LLP 122 EAST 42ND STREET SUITE 4000 NEW YORK, NY 10168			EXAMINER WHITE, DENNIS MICHAEL	
			ART UNIT	PAPER NUMBER
			1797	
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			11/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/552,752

Applicant(s)

KRETSCHMANN ET AL.

Examiner

DENNIS M. WHITE

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25, 27-39, 42-45, 47 and 48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25, 27-39, 42-45, 47 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Amendment filed 7/23/2009 is noted. Claims 26, 40-41, and 46 are cancelled. Claims 25, 29, 36-39, and 47 are amended. Claim 48 is new. Currently claims 25, 27-39, 42-45, and 47-48 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 39 recites the limitation, "a film suitable not adapted for re-closing the opening." It is unclear as to the metes and bounds of the claims. Is the applicant claiming some property of the film (i.e. it does not work after the first use and is thus not adapted for re-closing?) or is the applicant claiming that the film does not cover the opening, thus being adapted for closing the opening? The applicants show a film 16 in Fig. 15 that is not covering the opening. For the prosecution of claim 39, the office is reading the limitation as a film that does not cover the opening and is thus not adapted to re-close the opening.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1797

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 25, 27-39, 42-44, and 47-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Imburgia (USP 5,750,184).
6. Regarding claim 25, 34-35, and 47-48, Imburgia teaches a biological indicators for monitoring a sterilization cycle ("sterilization testing apparatus") comprising a biological indicator 10 ("housing") including a pathway 30 ("channel") comprising cavity 122 and 120 ("testing chamber having a base portion"), at the end of a tortuous path 36 ("supply line for supplying a sterilizing medium to the testing chamber" "base portion of the test chamber is formed at the end of the supply line") (Fig. 2, col. 6 lines 37-47), an indicator to produce a color change of the growth medium ("at least one indicator located in at least the testing chamber for indicating completion of sterilization") (col. 10 lines 14-24) that can be seen because the first member 16 and second member 18 ("the housing being comprised of an assembly of at least two superimposed parts") are clear ("at least one of the housing parts comprises a transparent material which makes the indicator visible without opening the housing"), the tortuous path 36 ("supply line") being comprised of a pathway ("channel") formed by the first and second members 16, 18 such as where the first member 16 has a channel 36a formed in a serpentine shape ("in at least one of the housing parts") (col. 6 lines 19-24), the pathway ("channel") having an opening at one end thereof communicating with the testing chamber and an opening 32 at the other end thereof for communicating with a source of the sterilizing medium outside the

Art Unit: 1797

housing (Fig. 2). Imburgia teaches the channel 36a is formed in first member 16 (Fig. 2) ("supply line"). The channel is defined by the sides ("ridges") of the first member 16. ("formed at least in part of a sidewall of at least one housing part and at least in part of one or more inwardly-facing ridges formed on an interior surface of at least one housing part"). Imburgia teach if the biological indicator is contemplated for use in a sterilization process requiring elevated temperatures, then the plastic will be selected from those materials having higher melting points, such as polycarbonate (col. 5 lines 30-34) ("housing parts fabricated of injection-moldable plastic" "having a heat resistance of at least 121 degrees C).

Regarding claim 27, Imburgia teaches a tortuous path with a length. It is noted that no length is specified, therefore the "length of the supply line relative to cross-section thereof is sufficiently great to prevent complete deaeration of the supply line during sterilization" is sufficiently broad to read on any length of the channel.

Regarding claim 28, Imburgia teaches the indicator is in the growth medium which is present in the pathway 30 ("a single indicator which extends over the entire length of the supply channel") (col. 10 lines 14-24).

Regarding claim 29 Imburgia teaches the indicator in the growth media and another indicator 44 distributed over the entire channel 30 (Fig. 2: 44 and 30) ("a plurality of indicators are distributed over the entire length of the supply channel").

Regarding claims 30, 33, Imburgia teaches the device is sealed by RF sealing ("apart from said opening communicating with a source of the sterilization

Art Unit: 1797

medium, the housing is hermetically sealed" "housing parts are fixedly secured together") (Abstract, col. 9 lines 41-46).

Regarding claim 31, Imburgia teaches the pathway ("supply channel") has parallel side edges (Fig. 2: 36) and is shown to have a uniform depth ("of square or rectangular cross-section") (Fig. 3: 36a).

Regarding claim 32, Imburgia teaches the pathway 30 comprises a tortuous path 36 ("the supply channel follows a spiral or meandering path") (Fig. 2).

Regarding claim 36, Imburgia teaches a perforations 150, 160, and 170 in the device 100 (Fig. 7) ("a breaking line along which the housing parts are manually breakable"). The perforations would provide access to the indicator in the pathway 30.

Regarding claim 37, Imburgia teaches an adhesive strip 42 ("at least one tear strip in the housing parts") (col. 8 lines 59-66). The tearing away of the adhesive strip ("tear strip") provides access to the indicator.

Regarding claim 38, Imburgia teaches opening 32 in one of the housing parts for providing access to the indicator and a flap 48 to retard fluid communication beyond the fold line ("openable closure for the opening") (col. 8 lines 64-68).

Regarding claim 39, Imburgia teaches the flap ("closure") comprises an adhesive strip ("a film suitable") that does not cover the opening ("not adapted for re-closing the opening" see 112 rejection above).

Regarding claim 42, Imurgia teach a chemical indicator 44 that is useful to indicate when the biological indicator 10 has been exposed to sterilizing conditions. ("scale" is sufficiently broad to read on any standard of measurement) applied by label 40 to member 18 ("applied to at least one of the housing parts") (col. 7 lines 30-32)

Regarding claim 43, Imurgia teach the device 10 ("housing") is comprised of label 40, first and second member 16 and 18, ("an assembly of at least three superposed parts") and the pathway 30 ("channel") is comprised of tortuous path 36 and pathway 38 ("at least two superposed sets of channels communicating with each other")

Regarding claim 44, Imurgia teach a user can separate one or more individual units of the assemblage 100 before use by the perforations 170 ("housing parts are detachable from each other") (col. and the second member 18 is then placed into contact with (for example, is lowered onto) first member 16 and adhered thereto, by conventional techniques, such as heat sealing or adhesive bonding. Examples of heat sealing include sealing through use of heated rollers, sealing through use of heated bars, radio frequency sealing, and ultrasonic sealing ("further comprising a seal between the housing parts") (col.5 line60-col. 6 line 3).

Regarding claim 47, Imurgia teach the device is made by the method for molding the first member to create cavities 20, 22 is through the use of a thermoforming process where materials are heated and then drawn or pushed into an appropriately shaped die using a vacuum or over-pressure. On contacting

Art Unit: 1797

the die, the material cools and retains its new shape. ("the housing parts comprise at least one injection molded heat-resistant plastic") (col. 5 lines 40-46).

7. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Imburgia (USP 5,750,184) in view of Browne (WO 01/56618 A1).

Imburgia teaches the limitations of claim 25 as per above.

Regarding claim 45. Imburgia teach the sealing of the first and second member can be heat sealing or adhesive sealing. Imburgia is silent about the seal comprises a mat.

Browne teaches a re-usable sterilization device comprising at least two parts which are releasably connected together. Browne teaches the separable components having grooves brought together during the connection of the components to define respective channels with the intermediate compressible member ("seal comprising a mat") allows for easy cleaning and airing of the grooved means. Hence, the device according to the invention can be both readily aired and cleaned while nevertheless being re-usable. (Pg. 11 lines 1-7). It is desirable to provide an intermediate compressible member for sealing in order to have a re-usable sterilization device.

Simple substitution of one known element for another to obtain predictable results is held to be obvious. Therefore, it would have been obvious to one of ordinary skill in the art, as motivated by Browne, to substitute the adhesive seal of Imburgia with the intermediate compressible member of Browne because they are known sealing members to seal the device components together with the

Art Unit: 1797

added advantage of allowing for the cleaning and airing of the device so it can be reused.

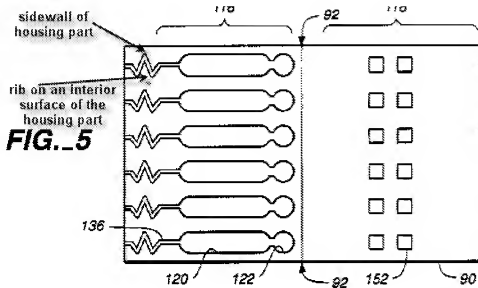
Response to Arguments

8. Applicant's arguments filed 07/23/2009 have been fully considered but they are not persuasive.

9. Applicants argue that amending claim 39 to depend from claim 38 removes any latent ambiguity that may have existed. It is noted that the ambiguity still remains because it is unclear if the "not adapted for re-closing the opening" is referring to the property of the film or is it not covering the opening.

10. Applicants argue that the indicator of Imburgia does not teach the indicator is made of metal, injection moldable thermoplastics or both because it is formed of flexible, deformable material. It is noted that Imburgia teach the indicator can be made of polycarbonate which is capable of being injection moldable.

11. Applicants argue that the tortuous path of Imburgia is fashioned entirely in one layer or planar part of the indicator and therefore does not teach at least a portion of the supply line (tortuous path) must be formed of a sidewall of one housing part and another portion (or the same portion) of the supply chamber must be formed of a rib on an interior surface of the same or a different housing part. It is noted that the "sidewall" is sufficiently broad to read on the side of the tortuous path that is on the outer part of the indicator, and the "rib on an interior surface" is sufficiently broad to read on the interior surface that defines the other side of the tortuous path (See Fig. 5 below.)



12. Applicants argue that the prior art drawing that is not clearly "to scale" cannot be considered to disclose particular dimensions. The argument is not within the scope of the claims. It is noted that no actual dimensions are claimed in claim 27, but that the length must be "sufficiently great to prevent complete deaeration of the supply line".

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

Art Unit: 1797

action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS M. WHITE whose telephone number is (571)270-3747. The examiner can normally be reached on Monday-Thursday, EST 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1797

/LYLE A ALEXANDER/

Primary Examiner, Art Unit 1797

/dmw/